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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,096	12/18/2001	Marian L. Kruzel	FDI004	3500

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EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,096	KRUZEL, MARIAN L.	
	Examiner	Art Unit	
	Stephen Gucker	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. The allowability of claims 1-3 is withdrawn based on the new art of record. The Examiner sincerely regrets that this art was not uncovered in the first Office Action on the merits.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batish et al. ("Batish") in view of Dickson et al. ("Dickson"). Batish describes methods where lactoferrin is used to inhibit the growth of potentially food-borne pathogenic and toxigenic organisms such as *Escherichia coli*, *Salmonella typhi*, and *Staphylococcus aureus* in culture. Batish also discloses that his research is in agreement with other researchers who reported that lactoferrin is effective against such food-borne pathogens as *Salmonella typhimurium* (pages 16-17). Batish does not disclose that these potentially food-borne pathogenic organisms could contaminate a meat product.

Dickson does disclose that *Escherichia coli*, *Staphylococcus aureus*, and *Salmonella typhimurium* do contaminate meat surfaces (abstract and pages 834-835) because of their attachment to lean muscle and fat due to the pathogens' hydrophobicity and surface charges. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Batish teaches that lactoferrin is effective against the same multiple food-borne pathogens that Dickson teaches contaminate meat surfaces by their hydrophobicity and surface charges. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the same microbes that are already known to attach or stick to the surface of meat carcasses (such as the germs that cause *E.coli* or salmonella food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the assay medium (page 18) used by Batish to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced

lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batish et al. ("Batish") in view of Stiles et al. ("Stiles"). The teachings of Batish are as set forth in **¶5** above. Stiles discloses that *E.coli* is a serious fecal and nonfecal contaminant from the skin or hides of animals during processing (pages 867 and 870-871). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Batish teaches that lactoferrin is effective against the same food-borne pathogen that Stiles teaches contaminates meat products at the wholesale and retail level. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the same microbe that is already known to be present in wholesale and retail meats (such as the germs that cause *E.coli* food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the assay medium (page 18) used by Batish to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-

by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

7. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batish et al. ("Batish") in view of Ryser et al. ("Ryser"). The teachings of Batish are as set forth in **¶5** above. Ryser discloses that gastroenteritis producing food-borne *E.coli* can be enteropathogenic, enterotoxigenic, enteroinvasive, or colohemorragic, and has long been recognized as responsible for numerous cases of infant and travelers' diarrhea (pages 948-949 and 953). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Batish teaches that lactoferrin is effective against the same food-borne pathogen that Ryser teaches causes infant and travelers' diarrhea, and sometimes death, from the consumption of raw or undercooked ground beef and ground beef sandwiches. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the same microbe that is already known to be present in raw or undercooked ground beef and ground beef sandwiches (such as the germs that cause *E.coli* food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the assay medium (page 18) used by Batish to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It

would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Dickson et al. ("Dickson"). Chander teaches that lactoferrin inhibits the growth of a variety of pathogenic and nonpathogenic micro-organisms such as *E. coli*, *Bacillus subtilus*, *Salmonella typhi*, *Vibrio cholerae*, *Shigella dysentriae*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* both *in vitro* and *in vivo* (pages 417-418). Chander does not disclose that these micro-organisms could contaminate a meat product. Dickson does disclose that *Bacillus subtilus*, *E. coli*, *Staphylococcus aureus*, and *Salmonella typhimurium* do contaminate meat surfaces (abstract and pages 834-835) because of their attachment to lean muscle and fat due to the pathogens' hydrophobicity and surface charges. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective against the same multiple variety of pathogenic and nonpathogenic micro-organisms that Dickson teaches contaminate meat surfaces by their hydrophobicity and surface charges. The economic and public health desire to reduce microbial

contamination by using a compound that is already known to be effective against the same microbes that are already known to attach or stick to the surface of meat carcasses (such as the germs that cause *E.coli* or salmonella food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

9. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Stiles et al. ("Stiles"). The teachings of Chander are as set forth in **¶8** above. Stiles discloses that *E.coli* and *Klebsiella pneumoniae* are serious fecal and nonfecal contaminants from the skin or hides of animals during processing (pages 867-868 and 870-871). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective

against both of these food-borne pathogens that Stiles teaches contaminate meat products at the wholesale and retail level. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the same microbe that is already known to be present in wholesale and retail meats (such as the germs that cause *E.coli* and *Klebsiella* food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

10. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Ryser et al. ("Ryser") in light of the definitions of "meat" from either Webster's dictionary or *WordNet ® 2.0*. The teachings of Chander are as set forth in **¶8** above. Ryser discloses that gastroenteritis producing food-borne *E.coli* can be enteropathogenic, enterotoxigenic, enteroinvasive, or colohemorragic, and has long

been recognized as responsible for numerous cases of infant and travelers' diarrhea (pages 948-949 and 953). Ryser also discloses that *Vibrio cholerae* which causes cholera is present in crab, shrimp, and oysters (pages 948-949 and 952-953), which meet the definition of "meat" as defined either by Webster's dictionary or *WordNet ® 2.0* (the instant specification does not define "meat product," so the Examiner had to rely on extrinsic sources to determine the metes and bounds of the claims). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective against both food-borne pathogens that Ryser teaches cause infant and travelers' diarrhea, cholera, and sometimes death, from the consumption of raw or undercooked crab, shrimp, oysters, ground beef and ground beef sandwiches. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the both microbes that are already known to be present in raw or undercooked crab, shrimp, oysters, ground beef and ground beef sandwiches (such as the germs that cause *E.coli* food poisoning and cholera) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food

product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

11. No claim is allowed.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571)-272-0961. The fax phone number for this Group is currently (571)-273-8300.

Stephen Gucker

June 3, 2005

BRENDA BRUMBACK
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